



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

February 3, 2005

**FILE COPY**

Ms. Kate C. Beardsley  
Ms. Carmen M. Shepard  
Buc & Beardsley  
919 Eighteenth Street, N.W  
Suite 600  
Washington, D.C. 20006

On behalf of Ranbaxy Laboratories Limited

Dear Ms. Beardsley and Ms. Shepard:

Your petition to the Food and Drug Administration regarding the 180-day exclusivity of simvastatin 80 mg tablet, was received by this office on 02/01/2005. It was assigned docket number 2005P-0046/CP1 and it was filed on 02/03/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0046

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